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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,372	10/19/2001	Lawrence A. Wolfrain	4239-61302	6866

7590 11/08/2002
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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,372

Applicant(s)

WOLFRAM ET AL.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-37 and 49-56, drawn to a functional TGF- β family fusion protein, isolated nucleic acid molecule, vectors, cells comprising the same, classified in class 536, subclass 23.1, for example.
 - II. Claim 38, drawn to a transgenic organism classified in class 800, subclass 9, for example.
 - III. Claims 39-41, drawn to a method of adding a non-native functionality to a mature biologically active TGF- β family protein, classified in class 435, subclass 69.1, for example.
 - IV. Claims 42-48, drawn to a method of treating a disease that responds to administration of a TGF- β family protein comprising administering a therapeutically sufficient amount of a fusion protein, classified in class 514, subclass 2, for example.
2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III and IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search

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and consideration of adding a non-native functionality to a mature biologically active TGF- β family protein, which is not required by the other Invention. Invention IV requires search and consideration of a method of treating a disease, which is not required by the other Invention.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The functional TGF- β family fusion protein of Invention I is independent and distinct from the product of Invention III because it is not required to make or use the functional TGF- β family fusion protein of Invention I. Additionally, the nucleic acid molecules, vectors, and cells of Invention I can be used in methods other than to make the functional transgenic organism of Invention II, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy or cell transplantation). Although, the transgenic organism of Invention III can be used in methods to isolate the nucleic acid molecule of Invention I, it can be used in materially different methods such as screening for therapeutic compounds (e.g. animal model).

5. Inventions I and each of III and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a

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materially different process of using that product. The polypeptide of Invention I can be used to isolate receptors.

6. Inventions II and each of III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of III and IV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III and IV do not recite the use or production of the transgenic animal of Invention II.

7. **FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:**

- A. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 8.
- B. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 9.
- C. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 10.
- D. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 11.
- E. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 12.
- F. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 13.
- G. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 14.
- H. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 15.
- I. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 17.
- J. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 18.
- K. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 21.

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- L. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 22.
- M. Claims 1-56, each in part, as the inventions pertain to SEQ ID NO: 24.
- N. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 25.
- O. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 26.
- P. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 27.
- Q. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 28.
- R. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 29.
- S. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 30.
- T. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 31.
- U. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 32.
- V. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 33.
- W. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 34.
- X. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 35.
- Y. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 36.
- Z. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 37.
- AA. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 38.
- BB. Claims 1-56, each in part, as the inventions pertains to SEQ ID NO: 39.

8. The inventions are distinct, each from the other because of the following reasons:

9. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions

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for the following reasons: Inventions A-Z, AA-BB, are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention A requires search and consideration of SEQ ID NO: 8, which is not required by any of the other Inventions. Invention B requires search and consideration of SEQ ID NO: 9, which is not required by any of the other Inventions. Invention C requires search and consideration of SEQ ID NO: 10, which is not required by any of the other Inventions. Invention D requires search and consideration of SEQ ID NO: 11, which is not required by any of the other Inventions. Invention E requires search and consideration of SEQ ID NO: 12, which is not required by any of the other Inventions. Invention F requires search and consideration of SEQ ID NO: 13, which is not required by any of the other Inventions. Invention G requires search and consideration of SEQ ID NO: 14, which is not required by any of the other Inventions. Invention H requires search and consideration of SEQ ID NO: 15, which is not required by any of the other Inventions. Invention I requires search and consideration of SEQ ID NO: 17, which is not required by any of the other Inventions. Invention J requires search and consideration of SEQ ID NO: 18, which is not required by any of the other Inventions. Invention K requires search and consideration of SEQ ID NO: 21, which is not required by any of the other Inventions. Invention L requires search and consideration of SEQ ID NO: 22, which is not required by any of the other Inventions. Invention M requires search and consideration of SEQ ID NO: 24, which is not required by any of the other Inventions. Invention N requires search and consideration of SEQ ID NO: 25, which is not required by any of the other Inventions. Invention O requires search and consideration of SEQ ID NO: 26, which is not required by any of the other Inventions. Invention P requires search and consideration of SEQ ID NO: 27, which is not required by any of the other Inventions. Invention

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Q requires search and consideration of SEQ ID NO: 28, which is not required by any of the other Inventions. Invention R requires search and consideration of SEQ ID NO: 29, which is not required by any of the other Inventions. Invention S requires search and consideration of SEQ ID NO: 30, which is not required by any of the other Inventions. Invention T requires search and consideration of SEQ ID NO: 31, which is not required by any of the other Inventions. Invention U requires search and consideration of SEQ ID NO: 32, which is not required by any of the other Inventions. Invention V requires search and consideration of SEQ ID NO: 33, which is not required by any of the other Inventions. Invention W requires search and consideration of SEQ ID NO: 34, which is not required by any of the other Inventions. Invention X requires search and consideration of SEQ ID NO: 35, which is not required by any of the other Inventions. Invention Y requires search and consideration of SEQ ID NO: 36, which is not required by any of the other Inventions. Invention Z requires search and consideration of SEQ ID NO: 37, which is not required by any of the other Inventions. Invention AA requires search and consideration of SEQ ID NO: 38, which is not required by any of the other Inventions. Invention BB requires search and consideration of SEQ ID NO: 39, which is not required by any of the other Inventions. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

10. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-IV. In order to be fully responsive, Applicant must elect one group from I-IV and one group from A-Z, AA-BB.

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11. **FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:**

- i. Tag
- ii. Targeting Moiety
- iii. Toxin
- iv. Enzyme
- v. Fluorescent peptide

12. The inventions are distinct, each from the other because of the following reasons:

13. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions (i) – (v), are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention (i) requires search and consideration of tags, which is not required by any of the other Inventions. Invention (ii) requires search and consideration of targeting moieties, which is not required by any of the other Inventions. Invention (iii) requires search and consideration of toxins, which is not required by any of the other Inventions. Invention (iv) requires search and consideration of enzymes, which is not required by any of the other Inventions. Invention (v) requires search and consideration of fluorescent peptides, which is not required by any of the other Inventions. Each functionalizing peptide portion requires a separate search of the literature databases. A search and examination

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of an Invention as it pertains to all functionalizing peptide portions would therefore present the examiner with an undue search burden.

14. Applicant is advised that this is not a requirement to elect a species. Rather, this is a **THIRD** restriction requirement superimposed upon the requirement to elect one group from I-IV, and one group from A-Z, AA-BB. In order to be fully responsive, Applicant must elect one group from I-IV, one group from A-Z, AA-BB, and one group from (i)-(v).

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmer

CJN
November 5th, 2002

ELIZABETH C. KEMMER
PATENT EXAMINER